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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,869

12/09/2003

Carl D. Wahlstrand

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

02/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No. 10/731,869	Applicant(s) WAHLSTRAND ET AL.	
	Examiner ALYSSA M. ALTER	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/07, 11/13/07</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 1/4/08 is also included</u> . |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed June 8, 2007 have been fully considered but they are not persuasive.

The Applicant argues that Berrang et al. does not disclose a first and second housing. On the contrary, Berrang et al. does in fact discloses two separate housings as disclosed in col. 3, lines 32-33, "said housing comprises two sections" and further refers to the housing as two housing sections. Therefore, Berrang et al. does disclose a first and second housing.

Furthermore, the Applicant argues that Berrang et al. does not teach an overmold. As stated in the previous Office Action, the examiner considers the pliable bridge to be an overmold. The bridge partially encapsulates, and thus unites, the edges of the two separate housings. This partial encapsulation can be seen in the figures, for example figures 2 and 4.

Also, the Applicant also argues that Berrang et al. fails to discloses a "hermetic interconnect member", as disclosed in claims 39. However as previously stated by the examiner, the pliable bridge unites the two housings and as a result acts as a hermetic interconnect member.

In addition, the Applicant argues that the "Office Action characterizes these coatings (gold, titanium, platinum, medical grade silocone, Berrang et al. col. 9, lines 58-62) as an overmold". However, the examiner does not consider the gold to be the overmold itself, but merely incorporated into the overmold, as detailed in the previous

Office Action. Therefore the overmold does comprise at least two materials, e.g. one being gold and the other being silicone.

In conclusion, the pending claims stand rejected under Berrang et al. as previously made of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

1. Claims 1-31 and 33-57 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638(US Patent Publication 20040176817 A1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

2. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/730,878 (US Patent Publication 20040176816 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two interconnected modules, each of the modules comprising a housing; and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,699 (US Patent Publication 20040172090 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two modules, each with a housing and coupling between the modules, wherein the coupling module permits motion of the two modules along at least one axis of motion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-54 of copending Application No. 10/730,873 (US Patent Publication 20040176814 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a plurality of interconnected modules each with a housing and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,867 (US Patent Publication 20040176673 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a plurality of interconnected modules with housings and an a flexible overmold concave along at least one axis that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 14-16 of copending Application No. 10/731,868 (US Patent Publication 20040173221 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a first module that includes control electronics within a first housing, a second module that includes a second housing and a flexible overmold that at least partially covers the first and second housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 6-9, 11-25, 27-30, 33-49, 51-54 and 56 stand rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. (US 6, 358, 281 B1). Berrang et al. discloses a first and second modules disposed within corresponding first and second housing in addition to the pliable (or bendable) bridge, which the examiner considers to be an overmold, that partially encapsulates the substantially cylindrical first and second housing as depicted in figure 1. The pliable (or bendable) bridge allows “the surgeon to bend said bridge so as to better fit the two housing sections to the curved surface of the skull”(col. 3, lines 35-37). Therefore the pliable bridge has a plurality of degrees of freedom. The examiner considers the first module to be housing 3, which contains the electronics 21 as seen in figure 2. The examiner considers the second module, to be housing 2, which contains the rechargeable battery 18.

In addition to the two modules in the overmold there is also an additional module, a housing for the coil 4 as seen in figure 1. Figures 15-18 depict the two modules and the third module, containing the coil, in alternative embodiments of linear and triangular

structure. In the triangular configurations, as depicted in figures 15 and 16, the third module, coil 4, is connected to the overmold by a flexible tether.

In figure 1, "the housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof"(col. 9, lines 58-62). Therefore the overmold does comprise at least two materials, e.g. one being gold and the other being silicone. 33

Also seen in figure 1, the proximal end of lead 8 connects to the lead connection module disposed within the overmold. The connection is between the bridge 6 and the lead junction 16. Lead 8 also has an electrode 10 disposed at the distal end.

As to claims 22, 38, 41 and 54, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 55 stands rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berrang et al. (US 6, 358, 281 B1). Since Berrang et al. discloses a totally implantable system, it would necessarily include a pulse generator that is associated with the electronics 21.

In the alternative, Berrang et al. discloses the claimed invention except for the pulse generator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electronics as taught by Berrang et al. with a pulse generator since it was known in the art to employ pulse generators in a completely implantable system, specifically auditory stimulation devices.

2. Claims 5, 10, 26, 31, 50 and 57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. (US 6, 358, 281 B1). Berrang et al. discloses the claimed invention except for a recharge coil that encircles both modules. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the coil around the two modules, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04)

As to claims 10, 31, 50 and 57, Berrang et al. et al. discloses the claimed invention except for the helix tether. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by

Berrang et al. with a helix shaped lead since it was known in the art that helix shaped leads reduce the slack in the lead.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
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